

REMARKS

The claims remaining in the application are claims 1-5, 10-13 and 15-25.

It is believed that support for all amendments made herein will be found either in the original claims or in obvious parts of the descriptive portion of the specification.

Claims 1-22 have been rejected under the second paragraph of 35 USC § 112 as being indefinite. This rejection is respectfully traversed.

It is believed that upon cursory examination the examiner will recognize that this amendment has corrected all of the aspects of indefiniteness pointed out by the examiner. There is a single exception, which shall here be discussed.

One of ordinary skill in the art of chemistry recognizes the term of art "multiply charged cations" as meaning a cation having more than one positive charge, e.g., Mg^{++} and Al^{+++} , as opposed to a singly charged cation, such as Na^{+} or K^{+} .

Any points of indefiniteness remaining in the claims reflect inadvertent errors, since applicants have made a good faith attempt to correct all of them. Applicants are amenable to a telephone conference initiated by the examiner to the undersigned if the examiner believes that such a conference would be of value in placing the claims in condition for allowance.

Claims 1-5, 7-10, 12, 13 and 15-17 have been rejected under 35 USC § 102(b) as being anticipated by Harreus et al., US 3,984,494 (Harreus). This rejection is respectfully traversed.

The examiner has accurately summarized the disclosure of Harreus at page 5 of

the office action. The disclosure of Harreus does not allow for the presence of monomer c) as required by the instant claims. Thus, this rejection is not sustainable.

In other words, the reference can not constitute an anticipation under 35 USC § 102, the requirements for which are set forth in MPEP § 2131 and the cases cited therein.

Claims 1-5, 7-10, 12, 13 and 15-17 have been rejected under 35 USC § 103 as being unpatentable over Harreus. This rejection is respectfully traversed.

The examiner's comments concerning optimization are not correct because the present claims requires monomer c) and can not represent an optimization of the reference, which does not include monomer c). *In re Sebek*, 465 F.2d 904, 907, 175 USPQ 93, 95 (CCPA 1972). See also *In re Antonie*, 559 F.2d 689, 195 USPQ 6, 8, 9 (CCPA 1977); MPEP § 2144.05(IIB) is also relevant.

Claims 1-5, 7, 10, 12, 13 and 15-17 are rejected under 35 USC § 103 as being unpatentable over Harreus in view of Cade et al., WO 98/27151 (Cade) . This rejection is respectfully traversed.

This rejection relies on the same asserted optimization relied on for the rejection under 35 USC § 103 over Harreus alone. As applicants have pointed out, the present claims are not within the generic disclosure of the reference and can not be a mere optimization. In the statement of the rejection the examiner has not explained why it would have been obvious to use certain additional monomers. Thus, there is no adequate explanation of the rejection on this record. See MPEP §§ 706.02(j) and

2143.02 and the cases cited in the latter. See also *Ex parte Levengood*, 28 USPQ2d 1300 (BPAI 1993). Thus, on this record, the rejection can not be maintained.

In addition to the fundamental errors discussed above, the following should be noted with respect to this rejection.

The entire disclosure of Cade is limited to capsules produced from cellulose ethers. The reasons why one of ordinary skill in this art would have considered it probable or even possible that the various disclosures of Cade relied on by the examiner would have been applicable to the polymers of Harreus is not apparent. In other words, the conclusion of obviousness drawn by the examiner is unsupported by a sufficient explanation. *Ex parte Levengood, supra*.

Claim 6 has been rejected under 35 USC § 103 as being unpatentable over Harreus in view of Boeckh et al., US 5,972,508 (Boeckh). This rejection is respectfully traversed.

Here again, the polymers of Boeckh, which do not include polyalkylene oxide polymer grafts, are sufficiently different so that an explanation is required for why one of ordinary skill in this art would have considered it appropriate to combine aspects of the two teachings.

In light of the foregoing amendments and remarks, it is believed that all of the rejections of record have been obviated, and allowance of this application is respectfully requested.

A check to cover the two month extension fee of \$400.00 is attached.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,

KEIL & WEINKAUF

A handwritten signature in black ink, appearing to read "Melvin Goldstein", written over the printed name.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Cancel claims 6-9, 14 and 22.

Amend claims 1-5, 10-13 and 15-21; and add new claims 23-25 as follows:

1. (amended) A hard capsule comprising

- (A) polymers [obtainable] produced by free-radical polymerization of
- a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of
 - b) polyether-containing compounds and
 - c) [where appropriate one or more] at least one other copolymerizable
[monomers] monomer c) selected from the group consisting of tert-butyl
acrylate, methyl methacrylate, ethyl methacrylate, isobutyl acrylate, tert-
butyl methacrylate, styrene, vinyl chloride, acrylic acid, methacrylic acid,
acrylamide and methacrylamide and subsequent at least partial hydrolysis
of the ester functions in the original monomers a),

[with the proviso that in the absence of another copolymerizable monomer c) the
polyether-containing compound b) must have a number average molecular weight
≤10,000,]

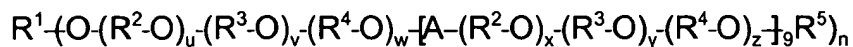
(B) [where appropriate] optionally, structure-improving auxiliaries and

(C) optionally other [conventional] constituents selected from the group consisting of
fillers, release agents, flow aids, stabilizers, water-soluble or water-insoluble dyes,
flavorings and sweeteners.

2. (amended) A hard capsule as claimed in claim 1, wherein the polymers (A) are

[obtainable] obtained by free-radical polymerization of

- a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of
- b) polyether-containing compounds of the general formula I



in which the variables have, independently of one another, the following meaning:

R¹ hydrogen, C₁-C₂₄-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-, polyalcohol residue;

R⁵ hydrogen, C₁-C₂₄-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

R² to R⁴ -(CH₂)₂-, -(CH₂)₃-, -(CH₂)₄-, -CH₂-CH(R⁶)-, -CH₂-CHOR⁷-CH₂-;

R⁶ C₁-C₂₄-alkyl;

R⁷ hydrogen, C₁-C₂₄-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

A -C(=O)-O-, -C(=O)-B-C(=O)-O-,
-C(=O)-NH-B-NH-C(=O)-O-;

B -(CH₂)_t-, arylene, optionally substituted;

n 1 to 1000 [(1-200)];

s 0 to 1000 [(0-200)];

t 1 to 12 [(1-12)];

u 1 to 5000 [(1-250)];

v 0 to 5000 [(0-250)];

w 0 to 5000 [(0-250)];

x 0 to 5000 [(0-250)];

y 0 to 5000 [(0-250)];

z 0 to 5000 [(0-250)];

and

- c) [where appropriate one or more] at least one other copolymerizable [monomers] monomer selected from the group consisting of tert-butyl acrylate, methyl methacrylate, ethyl methacrylate, isobutyl acrylate, tert-butyl methacrylate, styrene, vinyl chloride, acrylic acid, methacrylic acid, acrylamide and methacrylamide.

and subsequent at least partial hydrolysis of the ester functions in the original monomers a) [, with the proviso that b) in the absence of c) has a number average molecular weight between 300 and 10,000, and n-z have the values stated in parentheses].

3. (amended) A hard capsule as claimed in claim 1, wherein the polymers (A) are [obtainable] obtained by free-radical polymerization of

- a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of
b) polyether-containing compounds of the general formula I with a number average molecular weight of from 300 to 100,000, in which the variables have, independently of one another, the following meaning:

R¹ hydrogen, C₁-C₁₂-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-, polyalcohol

residue;

R^5 hydrogen, C_1-C_{12} -alkyl, $R^6-C(=O)-$, $R^6-NH-C(=O)-$;

R^2 to R^4 $-(CH_2)_2-$, $-(CH_2)_3-$, $-(CH_2)_4-$, $-CH_2-CH(R^6)-$,
 $-CH_2-CHOR^7-CH_2-$;

R^6 C_1-C_{12} -alkyl;

R^7 hydrogen, C_1-C_{12} -alkyl, $R^6-C(=O)-$, $R^6-NH-C(=O)-$;

n 1 to 8;

s 0;

u 2 to 2000 [(2-250)];

v 0 to 2000 [(0-250)];

w 0 to 2000 [(0-250)];

and

- c) [where appropriate] at least one or more other copolymerizable monomers selected from the group consisting of tert-butyl acrylate, methyl methacrylate, ethyl methacrylate, isobutyl acrylate, tert-butyl methacrylate, styrene, vinyl chloride, acrylic acid, methacrylic acid, acrylamide and methacrylamide.

and subsequent at least partial hydrolysis of the ester functions in the original monomers a) [, with the proviso that b) in the absence of c) has a number average molecular weight between 300 and 10,000, and u-w have the values stated in parentheses].

4. (amended) A hard capsule as claimed in claim 1, wherein the polymers (A) are [obtainable] obtained by free-radical polymerization of

- a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of
- b) polyether-containing compounds of the general formula I with a number average molecular weight of from 500 to 50,000, in which the variables have, independently of one another, the following meaning:

R¹ hydrogen, C₁-C₆-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

R⁵ hydrogen, C₁-C₆-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

R² to R⁴ -(CH₂)₂-, -(CH₂)₃-, -(CH₂)₄-, -CH₂-CH(R⁶)-,
-CH₂-CHOR⁷-CH₂-;

R⁶ C₁-C₆-alkyl;

R⁷ hydrogen, C₁-C₆-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

n 1;

s 0;

u 5 to 1000 [(5-250)];

v 0 to 1000 [(0-250)];

w 0 to 1000 [(0-250)];

and

- c) [where appropriate] one or more other copolymerizable monomers selected from the group consisting of tert-butyl acrylate, methyl methacrylate, ethyl methacrylate, isobutyl acrylate, tert-butyl methacrylate, styrene, vinyl chloride,

acrylic acid, methacrylic acid, acrylamide and methacrylamide.

and subsequent at least partial hydrolysis of the ester functions in the original monomers a) [, with the proviso that b) in the absence of c) has a number average molecular weight between 300 and 10,000, and u-w have the values stated in parentheses].

5. (amended) A hard capsule as claimed in claim 1, wherein the polymers (A) are [obtainable] obtained by free-radical polymerization of

- a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of
- b) polyether-containing compounds and
- c) [where appropriate 0 to 20% by weight of one or more other] at least one other copolymerizable [monomers] monomer selected from the group consisting of tert-butyl acrylate, methyl methacrylate, ethyl methacrylate, isobutyl acrylate, tert-butyl methacrylate, styrene, vinyl chloride, acrylic acid, methacrylic acid, acrylamide and methacrylamide.

and subsequent at least partial hydrolysis of the ester functions in the original monomers a), wherein the polyether-containing compounds b) have been prepared by polymerization of ethylenically unsaturated alkylene oxide-containing monomers, [and, where appropriate] alone or together with, other copolymerizable monomers.

10. (amended) A hard capsule as claimed in claim 1, wherein the resulting polymers are subsequently crosslinked [by a polymer-analogous reaction].

11. (amended) A hard capsule as claimed in claim [1] 10, wherein the resulting

polymers are subsequently crosslinked by reaction with one or more compounds selected from the group consisting of dialdehydes, diketones, dicarboxylic acids, boric acid, boric acid salts, and salts of multiply charged cations [are employed for the subsequent crosslinking].

12. (amended) A hard capsule as claimed in claim 1, wherein the structure-improving auxiliaries (B) employed are selected from the following classes of compounds:

- a) polymers with a molecular weight greater than 50,000
- b) substances which lead to crosslinking of the polymer chains of the polymers,
- c) and [, where appropriate,] substances which lead to crosslinking of the polymer chains of the structure-improving auxiliaries.

13. (amended) A hard capsule as claimed in claim 1, wherein the structure-improving auxiliaries employed are polymers [from the following classes of substances] selected from the group consisting of:

polyamino acids [such as gelatin, zein, soybean protein and derivatives thereof], polysaccharides [such as starch, degraded starch, maltodextrins, carboxymethylstarch, cellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylcellulose, carboxymethylcellulose, ethylcellulose, cellulose acetate, cellulose acetate phthalate, hydroxypropylcellulose acetate phthalate, hydroxypropylcellulose acetate succinate, hemicellulose, galactomannans, pectins, alginates, carrageenans, xanthan, gellan, dextran, curdlan, pullulan, gum arabic, chitin, and derivatives thereof,]

and synthetic polymers [such as polyacrylic acid, polymethacrylic acid, copolymers of acrylic esters and methacrylic esters, polyvinyl alcohols, polyvinyl acetate, polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers, polyvinylpyrrolidones and derivatives thereof].

15. (amended) A hard capsule as claimed in claim 1, wherein the [shell] capsule consists of 10 to 100% polymers of vinyl esters on polyether, [where appropriate] 0 to 80% structure-improving auxiliaries and [, where appropriate,] 0 to 30% said other [conventional] constituents.

16. (amended) A hard capsule according to claim 1, [obtainable] obtained by the dip process.

17. (amended) A hard capsule as claimed in claim 1 [,] which [comprises] has been packed with ingredients selected from the group consisting of one or more active pharmaceutical ingredients, vitamins, carotenoids, minerals, trace elements, food supplements, cosmetic active ingredients, crop protection agents, bath additives, perfume, flavoring, cleaner [or] and detergent.

18. (amended) A hard capsule as claimed in claim 1 [, wherein the shell] which capsule comprises from 20 to 80% of a polymer resistant to gastric fluid.

19. (amended) A hard capsule as claimed in claim [1] 18, wherein [a coating] said polymer resistant to gastric fluid is applied as a coating using [pharmaceutically customary] pharmaceutical coating processes [to achieve resistance to gastric fluid after production].

20. (amended) [The use of the] The hard capsule as claimed in claim [1 for] 17 which contains one or more pharmaceutical [applications] ingredients.

21. (amended) [The use of the] The hard capsule as claimed in claim [1 for cosmetic applications, applications in crop protection, or for cleaners or food supplements] 17 which contains one or more ingredients selected from the group consisting of cosmetics, crop protection agents, cleaning agents and food supplements.

23. (new) A soft capsule as claimed in claim 13, wherein said polyamino acids are selected from the group consisting of gelatin, zein, soybean protein and derivatives thereof.

24. (new) A soft capsule as claimed in claim 13, wherein said polysaccharides are selected from the group consisting of starch, degraded starch, maltodextrins, carboxymethylstarch, cellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylcellulose, carboxymethylcellulose, ethylcellulose, cellulose acetate, cellulose acetate phthalate, hydroxypropylcellulose acetate phthalate, hydroxypropylcellulose acetate succinate, hemicellulose, galactomannans, pectins, alginates, carrageenans, xanthan, gellan, dextran, curdlan, pullulan, gum arabic, chitin, and derivatives thereof.

25. (new) A soft capsule as claimed in claim 13, where said synthetic polymers are selected from the group consisting of polyacrylic acid, polymethacrylic acid, copolymers of acrylic esters and methacrylic esters, polyvinyl alcohols, polyvinyl

acetate, polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers, polyvinylpyrrolidones and derivatives thereof.